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EXAMINER

SKIBINSKY, ANNA

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Applicant's amendments to claim 28 and new claims 86-87 are acknowledged.
Claims 1-16 and 37-85 have been cancelled.

Priority

The priority date of the PCT/GB89/00460 filed 5/2/1989 is acknowledged.

Claim Election/Restriction

1. Claims 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/24/2006.
2. Newly submitted claims 28-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 28-36 stand withdrawn as belonging to non-elected Group II drawn to a method of making an array of oligonucleotides attached at different locations wherein the sequences are attached through a computer controlled printing device.
3. Newly submitted claim 88 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Group III is drawn to analyzing a polynucleotide by producing a labeled nucleic acid.
4. Newly submitted claim 89 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons Group V is drawn to comparing polynucleotide sequences under hybridization conditions.

5. Since applicant has received an action on the merits (filed 10/11/2006) for the originally presented invention, these invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-36, 88 and 89 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

The provisional rejection of claims 17-27, 37-41, 46-51 and 55-63 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 19, 21, 23, 26, 28-30 of Application No. 09/422,803 are withdrawn in view of the abandonment of 09/422,803 noted in applicant's Remarks filed 5/29/2007.

The provisional rejection of claims 37-41, 46-51 and 55-63 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-24, 26, 27, 29, 30, 38-39 of Application No. 09/422,804 are withdrawn in view of the abandonment of 09/422,804 noted in applicant's Remarks filed 5/29/2007

The provisional rejection of claims 17-27, 37-41, 46-51 and 55-63 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-26, 28-32, 49-52 and 59-60 of copending Application No. 10/115,077 are withdrawn in view applicant's Remarks filed 5/29/2007

Claim Rejections - 35 USC § 112

6. The rejection of claim(s) 17-27, 37-41, 46-51 and 55-63 for being vague and indefinite under 35 USC § 112-2nd paragraph in the Office Action filed 8/28/2007 is hereby withdrawn in view of Applicant's Remarks/Amendments filed 5/29/2007.

Claim Rejections - 35 USC § 103

1. The instant rejection is maintained from the previous Office Action filed 2/18/2007.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 17-27 and 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. (P/N 4,994,373 claiming a priority date of 5/9/1985) and further in view of Matkovich et al. (P/N 4,828,386 claiming a priority date of 6/19/1987).

4. Stavrianopoulos et al. teach fixing single and double stranded oligonucleotide sequences to nonporous solid supports made of glass (col. 1, lines 25-41; and col. 5, lines 37-57). Stavrianopoulos teaches an array comprising predetermined sequences. For example, DNA from specific samples, such as lambda DNA (column 9, line 51) or adenovirus DNA (column 11, line 21) is used as analytes for attachment to the array.

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Glass plates with depressions or wells (i.e. cells) are taught (col. 8, Example 1), as in claims 17, 19, 20, and 86. Oligonucleotides or oligonucleotide probe sequences (col. 5, line 58 to col. 6, line 4) are covalently attached to the support after the glass has been treated with a silane linker for covalent attachment (col. 8, Example) and wherein the DNA can hybridize to the plates (col. 12, example 7) which involves the binding with terminal nucleotide, as in claim 23 and 24.

5. Further, Stavrianopoulous et al. shows use of conventional microtiter plates to contain samples (col. 12, lines 20-24), with examples that show a capacity of 3×10^{-12} mmol of oligonucleotide, as required by claim 22.

6. Stavrianopoulos et al. teaches in situ techniques (col. 5, lines 41-46) for attaching the nucleotide sequence, as required by claim 25.

7. Regarding the limitations of claims 26, 27 it is brought to Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See MPEP 2113.

8. Stavrianopoulos et al. teaches (col. 1, lines 29-30 and col. 5) an array of oligonucleotides with a substrate that may be plastic or glass and that various (i.e. different) polynucleotide samples may be present in the array (col. 8, lines 40-45).

9. Stavrianopoulos et al. does not teach a microporous material attached to the impermeable surface, as required in claims 17 and 18.

10. Matkovich et al. teaches the use of a microporous membrane on top of a support (Abstract; col. 3, lines 2-33) which can be used to bind biologically active substances

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including nucleic acids (col. 6, lines 32-60). Furthermore, Matkovich et al. also teach covalent binding of a macromolecular reactant to the reaction layer by covalent binding (col. 4, line 60 to col. 5, line 1), as required in claim 17 and 86.

11. Further, Stavrianopoulous et al. shows use of conventional microtiter plates to contain samples (col. 12, lines 20-24) but does not show the number of wells to be between 72 and 1.1×10^{12} cells as required by claim 21.

12. Matkovich et al. shows microtiter plates with 96 wells via an 8x12 matrix of wells (col. 1, lines 23-26).

13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus taught by Stavrianopoulous et al. to insert a porous membrane as taught by Matkovich et al. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Stavrianopoulous et al. to use the 96 well microtiter plate of Matkovich et al. for the purpose of analyzing an array of up to 96 samples. One of ordinary skill in the art would be motivated to use the porous membrane on top of the impermeable surface of Stavrianopoulous et al. because Matkovich et al. teach that a porous surface results in a better binding capacity of biological substances (Matkovich et al., col. 3, lines 13-19). One of ordinary skill in the art would have a reasonable expectation of success of using a porous surface with the impermeable surface of Stavrianopoulous et al., because Matkovich et al. teaches that the porous surface may be placed on top of a backing (Matkovich et al., col. 3, lines 22-28).

Response to Arguments

14. Applicant's arguments filed 5/29/2007 have been fully considered but they are not persuasive.

15. Applicants argue that Stavrianopoulos in view of Matkovich et al. do not teach "an array of oligonucleotides with predetermined sequences".

16. In response, as reiterated in the rejection above, Stavrianopoulos teaches an array comprising predetermined sequences. For example, DNA from specific samples, such as lambda DNA (column 9, line 51) or adenovirus DNA (column 11, line 21) is used as analytes for attachment to the array. The sequence is predetermined in the sense that it is from a certain sample, therefore the predetermination of "which sequences" will be arrayed is known. The specification does not provide a specific definition for the term "predetermined" sequence to be a "known sequence" or a sequence whose base composition is known, therefore, teachings in Stavrianopoulos that DNA from specific samples, such as lambda DNA (column 9, line 51) or adenovirus DNA (column 11, line 21) is used as analytes for attachment to the array anticipates the instant claims. Further, the description by Stavrianopoulos of "various" single stranded analytes for use in an array for hybridization is reasonably interpreted as being different oligonucleotides, as is claimed.

17. Applicants argue that Stavrianopoulos in view of Matkovich et al. do not teach a covalent attachment of oligonucleotides.

18. In response, Stavrianopoulos et al. teaches treatment of the array with a silane linker (the gamma-aminopropyltriethoxysilane of Example 1) for covalent attachment of

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DNA. Furthermore, as admitted by Applicants, Matkovich et al. teaches covalent binding of a macromolecule to the microporous surface (col. 4, line 60 to col. 5, line 1).

19. Applicants argue that the art of Stravrianopoulous and Matkovich are combined in hindsight and that one of skill in the art would not look at Matkovich to improve DNA assays because Matkovich teaches the binding of antibodies, not DNA, to porous materials (Remarks, page 10).

20. In response, Matkovich et al. provides motivation to combine the porous materials with the glass surface array of Stravrianopoulous et al. by teaching that a porous surface results in a better binding capacity of biological substances (Matkovich et al., col. 3, lines 13-19). It would therefor be obvious to one of skill in the art that the binding of DNA, a biological substance, would benefited by the porous material as taught by Matkovich et al. Further, Matkovich et al. teach that the porous material may be placed on top of a backing (Matkovich et al., col. 3, lines 22-28). It would have been obvious to one of skill in the art to place the porous material as taught by Matkovich on top of a backing such an array surface.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call
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